REMARKS

Initially, Applicants would like to thank the Examiner for granting the telephone interview on December 8, 2004, and agreeing to review a supplemental reply to the final Office Action dated May 12, 2004 and the Advisory Action dated November 26, 2004.

In the final Office Action, the Examiner maintained the rejection of pending claims 1-6, 8-12, 20, and 21 (drawn to a retroviral vector, cells containing it, and a related system) for lack of enablement. According to him, the claims read on using the claimed matter for gene therapy.

In the response to the final Office Action, Applicants pointed out that the present case mirrored "Example G: Gene Therapy" in the "TRAINING MATERIALS FOR EXAMINING PATENT APPLICATIONS WITH RESPECT TO 35 U.S.C. SECTION 112, FIRST PARAGRAPH-ENABLEMENT OF CHEMICAL/BIOTECHNICAL APPLICATIONS" ("Training Materials"). Claim 1 in Example G is drawn to a viral vector. Analysis regarding claim 1 reads:

> The specification discloses an in vitro use for the viral vector of claim 1 and clearly discloses how to make and use the viral vector in the in vitro environment. Since claim 1 does not recite any environment of use, only one enabled use covering the scope of the claim is needed to enable the claim. Therefore, the disclosure with respect to the in vitro use of the viral vector is sufficient to enable claim 1 and it would be inappropriate to include claim 1 in a rejection under 35 U.S.C. 112, first paragraph.

As in Example G, (i) claims 1-6, 8, and 9 of the present application are also drawn to a viral vector; (ii)"[t]he specification discloses an **in vitro use** for the viral vector," e.g., to transiently transect cell lines and to express a recombinant protein at a high level in particular cell lines (see, e.g., page 17, line 23 through page 18, line 23 of the Specification; emphasis added); and (iii) "[the] claim[s do] not recite any environment of use." Thus, claims 1-6, 8, and 9 meet the enablement requirement. For the same reasons, claims 10-12, 20, and 21, which cover cells and systems containing the viral vector, also meet the requirement.

Nonetheless, the Examiner asserted in the Advisory Action that "[t]he specification fails to specifically [state] the use of the claimed viral vector for [in vitro purposes, such as] making recombinant protein." See the Advisory Action, page 3, lines 5 and 6.

During the above-mentioned interview, Applicants' counsel reiterated the supporting passage, and further pointed to working examples presented in Figs. 2a-10b of the Specification. As shown in the figures, the claimed vectors were **used in vitro** to express recombinant proteins, such as EGFP, in various cell lines. Clearly, contrary to the Examiner's assertion, the Specification specifically states use of the claimed viral vector for in vitro purposes, e.g., for expressing recombinant protein in cell lines.

In the Advisory Action, the Examiner contended that "the eventual purpose of the claimed retroviral vector is for gene therapy in vivo..." During the interview, Applicants' counsel reminded the Examiner that, according to the Training Materials, claim 1 in Example G discussed above should not be rejected under §112, first paragraph in view of "an **in vitro use** for the viral vector of claim 1," even though this viral vector "can be used ... in vivo for medicinal use, such as gene therapy."

For the above discussed guidelines and facts, the Examiner agreed to reconsider this case and suggested that Applicants file a supplemental response.

Separately, in the Advisory Action, the Examiner raised a new ground for the rejection, contending that "[t]he specification fails to provide adequate guidance and evidence for how to use various HERV-LTRs in a retroviral expression vector..." See, the Advisory Action, page 3, lines 15 and 16. Applicants would like to point out that, contrary to the Examiner's position, the Specification provides ample general guidance and actual working examples on how to use various HERV-LTRs. See, e.g., the paragraph bridging pages 8 and 9; and page 14, line 28 through page 21, line 31, respectively. Thus, the Examiner's ground is untenable.

CONCLUSION

In view of the above remarks, as well as the remarks provided in the last response, Applicants submit that all pending claims meet the enablement requirement. Thus, it is submitted that allowance of this application is proper, and early favorable action is solicited.

Please apply any other charges to deposit account 06-1050.

Respectfully submitted,

Date: 12-09-2004

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